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Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Nisseiken Avian Colibacillosis Vaccine
Company Name: Nisseiken Co., Ltd.
Address: 9-2221-1 Shin-machi, Ome, Tokyo 198-0024, Japan
Tel.: +81-428-33-1001
Responsible Dept.: Business department
Tel.: +81-428-33-1003
Fax.: +81-428-33-1130
Recommended Use/Restriction of Use: Veterinary medicinal products

2. HAZARDS IDENTIFICATION

Most Important Hazard: None
Hazards: None
Environmental Impact: No data available
Physical and Chemical Hazards: None
Specific Hazards: None
Main Symptoms: None
Classification Name: None
Summary of Expected Emergency: None

3. COMPOSITION/INFORMATION ON INGREDIENTS

Single Component or Mixture: Mixture

Generic name: Avian *Escherichia coli* live vaccine

Ingredients and Contents: Per 1,000 doses of the vaccine

Component Name	Contents	CAS No.
(1) Avian <i>Escherichia coli</i> serotype O78, AESN1331 strain	1×10^{10} - 1×10^{12} CFU	Not applicable
(2) Skim milk	100 mg	Not applicable
(3) Yeast extract	1.3%	8013-01-2
(4) D-Sorbitol	2.5%	50-70-4

Chemical Properties (chemical formula):

(1) - (3); Not applicable

(4); $C_6H_{14}O_6$

Official Gazette Notification Reference Number (Chemical Substances Control Law):

(1) - (3); Not applicable

(4); 8-50

Components Contributing to the Hazard: Not applicable

Impurities Contributing to the Hazard: Not applicable

4. FIRST AID MEASURES

In Case of Inhalation: Expose the users to fresh air and, if necessary, seek medical treatment with a description attached to the product.

In Case of Contact with Skin: Wash out with soap and water as necessary, and disinfect with 70% alcohol.

In Case of Contact with Eye: Flush with water or warm water and, if necessary, seek medical treatment with a description attached to the product.

In Case of Ingestion: Wash the mouth well with water and, if necessary, seek medical treatment with a description attached to the product.

Brief Information Concerning the Most Important Signs and Symptoms: Not applicable

Protection for Persons who Practice First Aid Measures: Not applicable

Special Precautions for Doctor: Not applicable

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Water, sand, carbon dioxide, and dry chemical powder or foam

Extinguishing Media to Avoid: Not specified

Specific Hazards Arising from the Product: Not applicable

Specific Fire-Fighting: Spread extinguishing media to the fire sources.

Protection for Persons Who Extinguish a Fire: Not specified

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: No data available

Environmental Precautions: No data available

Methods for Cleaning Up: Collect in a vessel as much as possible, and disinfect with 70% alcohol.

Prevention of Second Accident: No data available

7. HANDLING AND STRAGE

Handling:

Technical Measures: Not applicable

Precautions:

(1) Do not use the product with any abnormal appearance and content.

(2) Do not use the vaccine after expiry.

(3) Do not add other medicinal products (vaccines) to the product.

(4) Use sterilized or boiled sprayer or coarse sprayer.

Do not use ones disinfected with chemical agent (except for gas sterilization) or contaminated by other medicine. When sterilize injection devices by dry heat, steam or boiling, use them after they return to ambient temperature.

(5) Shake well to homogenize the vaccine before using it.

(6) Before use, disinfect a rubber cap of the lyophilized vaccine container, insert about 4 mL saline for 1,000 doses into it, and shake well to dissolve uniformly.

(7) Insert a sterilized needle into the rubber cap, absorb the dissolved vaccine and insert into a bottle of a fine or coarse sprayer. Read an instruction of the fine or coarse sprayer when using them, and follow the precautions.

(8) Avoid physical damage to the vaccine vial, because it may break due to vacuum.

(9) Cautions should be taken not to cut your fingers with the cut section of the aluminum cap when opening the vial.

Safely Handling Precautions:

Precautions:

(1) Worker shall use of protective barriers (e.g., eye protection, mask, and gloves) to protect one's body.

(2) Wash hands well with soap after handling.

Storage:

Appropriate Storage Conditions:

- (1) Store in light-resistant containers below 10 °C.
- (2) Keep the product out of children's reach.
- (3) Avoid direct sunlight because it influences the product quality.

Safe Packaging Materials: No data available

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Appropriate Engineering Controls: No data available

Occupational Exposure Limit: No data available

Administrative Exposure Limit: No data available

Protective Equipment

Respiratory Protective Equipment: Not applicable

Hand Protection: Not applicable

Eye Protection: Not applicable

Skin and Body Protection: Not applicable

Appropriate Hygiene Measures: No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State

Shape: Solid

Color: Pale yellow-grayish brown to pale yellowish gray colored dried material. When reconstituted with physiological saline and mixed, it turns to pale yellowish gray colored homogeneous opaque liquid.

Odor: Odorless

pH: No data available

Physical State Changing Specific Temperature/Temperature Range

Boiling Point: No data available

Boiling Range: No data available

Melting Point: No data available

Decomposition Temperature: No data available

Flash Point: No data available

Ignition Point: No data available

Explosive Properties: Not applicable

10. STABILITY AND REACTIVITY

Stability: No data available

Reactivity: No data available

Conditions to Avoid: No data available

Materials to Avoid: No data available

Hazardous Decomposition Products: No data available

Others: No data available

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: No data available

Local Effect: No data available

Sensitization: No data available

Chronic/Long-Term toxicity: No data available

Carcinogenicity: No data available

Mutagenicity: No data available

Teratogenicity: No data available

Reproductive Toxicity: No data available
Others: Not applicable

12. ECOLOGICAL INFORMATION

Mobility: No data available
Persistence/Degradability: No data available
Bioaccumulative Potential: No data available
Biototoxicity: No data available
Fish Toxicity: No data available
Others: No data available

13. DISPOSAL CONSIDERATIONS

Dispose the left over vaccine and used bottles in accordance with laws enacted by a local public entity, or process them as infectious waste after disinfection or sterilization. Flush the used apparatus with water after sterilizing.

14. TRANSPORT INFORMATION

International Regulations: No data available
UN Class: No data available
UN No.: No data available
Domestic Regulations: No data available
Additional Regulations: No data available
Specific Safety Measures and Conditions for Transport: No data available

15. REGULATORY INFORMATION

The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof: Not applicable

16. Other Information

- (1) This drug is specified as powerful drug in The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.
- (2) This product should be used only pursuant to the prescription or direction of a veterinarians, because it is a prescription drug.
- (3) Confirm precautions mentioned in a description attached to the product before use.
- (4) In case of accidental exposure of the vaccine in your eyes, nose, or mouth, flush the exposed parts with water. If necessary, seek medical advice and show the package insert or the label to the physician.

The information above is believed to be accurate and represents the best information currently available to us for safe handling, use, treatment, store, transport, disposal, and accidental release measures of this product. However, it is not to guarantee anything and not to specify the quality.